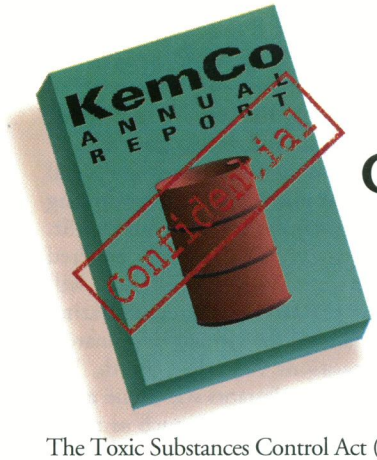

Can You Keep a Secret?

The Toxic Substances Control Act (TSCA) of 1976 was designed to identify and control chemicals that might pose a public health risk, but chemical manufacturers have consistently taken advantage of the law's confidentiality provisions to withhold data from the public. The liberal exemptions claimed by industry, however, have not gone unnoticed by state environmental regulators, public interest groups, and scientists. Growing criticism of the law's confidential business information (CBI) provision is now leading to reform efforts in which industry is participating.

In the environmental legislation of the 1970s, aimed specifically toward improving land, water, and air quality by focusing on the release of chemicals, TSCA took aim at chemical manufacture itself. In a new book, *Reducing Toxics: A New Approach to Policy and Industrial Decisionmaking*, compiled by the Pollution Prevention Education and Research Center at UCLA, TSCA is called the "jewel in the crown of environmental protection" because of its vast potential for preemptive action. TSCA requires that manufacturers notify the EPA of the production of specific chemicals, including those in premanufacturing stages, and their potential for effects on public health and the environment. It also empowers the EPA to step in and halt the manufacture of those chemicals if the agency believes that the information the manufacturers provided was insufficient.

However, TSCA also recognizes the competitive reality of the marketplace by extending to manufacturers the right to claim some of the information on chemicals as confidential. Although manufacturers are still required to submit information on chemicals being manufactured or planned, they can request that the submitted data be classified as confidential business information for purposes of maintaining trade secrets and competitive advantages that often are the result of costly research investments.

Too Tolerant?

By all accounts, the EPA has been very tolerant of these requests. During the two decades of TSCA data collection, "EPA has thoroughly adhered to the confidentiality process, maintaining CBI protection as if national security secrets were at stake," according to Janice Mazurek, Robert Gottlieb, and Julie Roque, authors of a chapter in *Reducing Toxics*. "At the same time, however, CBI claims by industry during this period have become so excessive that they, more than any single aspect of the act's implementation, have fundamentally frustrated the intent of TSCA and transformed a treasure trove of information potentially available for pollution prevention into a guarded fortress of inaccessible data."

Foremost among those who seek access to these data are state environmental agencies, many of whom have been performing their own risk assessments over the last 20 years, but who are excluded from access to the confidential information held by the EPA. In large part, the exclusion of state regulators from the notification process may be a reflection of the period during which TSCA was born. "When TSCA was enacted in 1976, the states were only in their infancy in handling a lot of sensitive scientific and commercial-type information," says Paul Wright, a senior attorney with the Dow Chemical Company. "Back in 1976, nobody was handling it, really, except the companies." Today, according to Roger Kanerva, environmental policy advisor to the Illinois EPA, more than half the states have some type of legislated pollution-prevention programs, and a 1993 needs assessment by the Forum on State and Tribal Toxics Action found that 82% of the respondents (48 states responded) reported anywhere from 1 to 6 ongoing toxics regulations programs.

According to Scott Sherlock, a lawyer in the information management division of the EPA's Office of Pollution Prevention and Toxics (OPPT), the realization that states should be parties to CBI became widely shared within a few years after TSCA's passage. In fact, when Congressman David Durenberger (R-Minnesota) sought to amend TSCA in 1984 with a bill that was perceived as being industry friendly, the legislation sought to include states as recipients of the CBI information.

In subsequent years, TSCA has continued to attract attention and criticism, mostly from environmentalists and mostly for failure to live up to initial expectations. Essentially, critics argue that TSCA simply has not resulted in the envisioned chemical control. They also point to the extensive CBI privilege being claimed by industry and the fact that information is not getting to the states. According to Sherlock, in 1990 the EPA sought to "revitalize" TSCA in several ways, including "an effort to reduce CBI claims." The EPA embarked on a specific CBI reform program designed, in Sherlock's words, "to examine CBI, what kinds of claims are made, and also examine how the claims are made and whether they're reasonable under the statute."

The CBI language in TSCA is contained in Section 14(a), which limits confidentiality to "trade secrets or financial information" and Section 14(b), which restricts confidentiality to data that disclose "processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture . . . any data which discloses the portion of the mixture comprised by any of the chemical substances in the mixture." No matter what the original intent was, it has become routine for industry to claim confidentiality for chemicals which they are required to list in the premanufacturing notices, or PMNs, they are required to submit to the EPA. "There's an assumption that anything claimed as confidential is a valid claim," says Sherlock, "and therefore, in order for us to limit the claims, we have to actually physically go after them. Since we get over 2,000 PMNs a year and 99 percent of those have CBI claims, it's a problem for us."

Part of the EPA's revitalization effort was a contract with a consultant, Hamp-

shire Research Associates, Inc., to specifically address CBI's influence on TSCA implementation. The Hampshire report, published in March 1992, was highly critical of the leniency with which CBI designations had been granted. "EPA practices for safeguarding CBI have effectively prevented damage to submitters from disclosure," the report stated, "but EPA appears to be providing protection to a considerable body of data that is not entitled to such protection; thus resources that could be applied to the protection of legitimate trade secret information are presumably being diverted for the protection of frivolous claims."

A Plan of Action

The Hampshire report initiated a series of EPA public meetings, a process which included chemical industry representatives—in particular, the Chemical Manufacturers Association (CMA)—as participants in the development of proposals for change. The result was an action plan that was released in June 1994 as a statement of "specific actions the Office will undertake to reduce inappropriate CBI claims." Essentially, the plan is a series of methods for the EPA to reduce inappropriate claims, such as educational workshops and communication of examples of appropriate and inappropriate CBI claims.

Also in 1994, Congressman Harry M. Reid (D-Nevada), chair of the Senate's Subcommittee on Toxic Substances, Research and Development of the Committee on Environment and Public Works, called for a TSCA reauthorization hearing and a report from the General Accounting Office on the effectiveness of the law. Among its findings, the GAO reported that although TSCA has resulted in an inventory of some 72,000 chemicals, its track record for regulating them has been limited to controlling nine chemicals determined to pose unreasonable health risks.

The GAO identified an inherent problem in TSCA's power to restrict chemical manufacture: "the act's legal standards are so high that they have usually discouraged EPA from using these authorities." The report noted that a 1991 ruling by the U.S. Court of Appeals for the Fifth Circuit held that the burden is on the EPA to justify that the products it bans present an unreasonable risk. The GAO report states: "To make an unreasonable risk determination, the act requires EPA to consider more than whether the chemical is toxic or harmful to humans, animals, plants, and other organisms. The agency is to also determine the magnitude of human and environmental exposures to the chemical. Once it determines the extent of the risks presented by the chemical, EPA must determine whether these risks are unreasonable. According to EPA officials, the agency must, in effect, perform a cost-benefit analysis, considering the economic and societal costs of placing controls on the chemical." The report also found that confidentiality claims are "excessive" and that states should have access to CBI because it "would provide the public with another line of defense to protect health and the environment."

After the Republican sweep in the midterm elections last November, it became obvious that TSCA reauthorization was a dead issue for the time being; the EPA's only new direction on TSCA would be provided by its action plan. While the plan didn't specify any definite proposals to extend CBI to state regulatory agencies, it did refer to discussions between OPPT, the Forum on States and Tribal Toxic Action (FOSTTA, an EPA-sponsored group), and the CMA, and the exploration of potential ways for states to receive CBI.

The result of the discussions, completed this spring, is a pilot project that will involve six states. Alabama, California, Georgia, Illinois, New York, and Wisconsin will receive CBI information from the EPA for a 60-day period and then submit reports on how it will affect risk assessments in those states. The CMA is taking credit for the plan, which gets around TSCA's statutory restrictions on dissemination of confidential data by naming the states as federal contractors allowed to access CBI.

Kanerva had been pushing for states to receive CBI ever since the early 1980s, when his agency sought to develop a comprehensive toxics control strategy and contacted the EPA about chemical production in Illinois, only to run into the locked door of CBI. "How could we hope to ultimately ensure chemical safety to citizens in Illinois if we were not even able to find out what chemicals were in production and use?" asked Kanerva when he testified last year at one of the TSCA reauthorization hearings. "From that time forward, CBI became a symbol for us of poor public policy that needed to be changed." Kanerva also argues that the evolution of such environmental "right-to-know" laws as the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 have rendered TSCA somewhat of an anachronism. He points out that EPCRA also recognizes the need for confidential information, but does not presume protection for trade secrets like TSCA does. According to Kanerva, EPCRA allows states to obtain "any information" that is submitted to the federal EPA for an EPCRA confidentiality request.

According to Wright, industry's interest in the issue of CBI sharing with states arose about two years ago when TSCA was coming up for reauthorization, and arguments like Kinerva's found sympathetic ears. "We felt it was sort of a nonsensical situation," Wright said. "If the state could get it from us directly [under a revised TSCA], they probably ought to be able to get it from U.S. EPA. EPA, though, took the position that they weren't permitted under TSCA to allow states access to it because the statute reads that federal employees and federal contractors are the only ones who can have access to it."

Essentially then, according to Wright, when the CMA came up with the contractor plan, they came up with a legal theory that means "we don't have to wait for Congress." The chemical industry's central concern is one of efficiency. That is, if a revised TSCA would require chemical manufacturers to submit CBI to any state that asks for it, "then instead of us supplying information to one government entity—the U.S. EPA—we'll be submitting it to 51 government entities—the U.S. EPA plus all 50 states," Wright said. "That kills a lot of trees to print the paper, but it doesn't accomplish anything."

The Effect of Sharing

Wright says that chemical manufacturers recognize the interest that states have in CBI data, but he contends that confidential information must continue to be liberally designated as such—including chemicals in all premanufacturing notices. "I have to continue to protect that information as confidential," he said, "because if I don't and my competitors get hold of it, then I've invested tens of millions of dollars in research and I won't be able to recoup it because everybody in the world is going to know about it. You have to worry about shareholder value and shareholder derivative value if you start giving away the company property. There's a well-founded legal principle of intellectual property and rights to that property. If we give away that property, it's the same as if we give away a 50-acre tract of land."

The CMA Director of Product Stewardship Charles Walton agrees that states deserve access to CBI, but only so long as the information truly remains confidential. "We want to make sure that this information is fully protected and is not disclosable based on any circumstances that states may come up with," he said.

One of CMA's concerns, he said, involves freedom of information statutes and whether a freedom of information request might provide an avenue for competitors to gain access to confidential information.

Walton and Wright both downplay the effect that sharing CBI with states will have, but they concede that chemical manufacturers have filed too many CBI requests. Wright says that improper CBI requests are more the result of ignorance than intent. "For instance," Wright said, "some companies didn't know that they could claim one sentence or one word in a document as confidential; they felt they had to claim the whole document." He said that the CMA has responded by holding workshops on how to draft CBI requests "as narrowly as you can."

While the EPA and industry may be making strides in reducing improper CBI claims and expanding the confidential data to state regulators, some observers say these are efforts that would be made unnecessary by a stronger law. Janice Mazurek, a research associate at the Washington, DC-based Resources for the Future, a nonpartisan environmental policy group, assesses TSCA as "a missed opportunity for pollution prevention." Said Mazurek, "If you go back and look at what the original framers intended, TSCA was really supposed to be the statute that collected information about development, production, and use of toxic substances." TSCA's framers recognized the need for CBIs, she continued, "but I think that EPA, for lack of will, really loosely interpreted what did and didn't constitute confidential business information over the years since it was implementing TSCA, and it hasn't been until the last four or five years that EPA has begun to sit down with industry and other stakeholders and make them aware of some of these problems and, for example, challenge egregious CBI claims."

Now that the chances for statutory changes to TSCA are dead—for the moment, at least—the current efforts by both the EPA and industry to reduce CBIs and extend that information to a few states is at least a sensible alternative. "Let's face it," Mazurek said. "The train is obviously heading down the tracks to devolution of tough federal environmental responsibility and a greater role for the states. One of the greatest obstacles we're finding in our research here at [Resources for the Future] is that under most of the statutes there simply isn't enough adequate monitoring data. Certainly TSCA, as the Hampshire study showed, caused EPA to collect the most comprehensive health and safety database available anywhere in the country, and states that can demonstrate that they can provide the same kind of protection of confidential information should certainly have access to that."

Richard Dahl

PREVENTIVE STRATEGIES FOR LIVING IN A CHEMICAL WORLD
An International Symposium

Sponsored by the
COLLEGIUM RAMAZZINI

November 3-5, 1995 ♦ The Omni Shoreham Hotel ♦ Washington, DC

On November 3-5, 1995, in Washington, DC, the Collegium Ramazzini will convene the 1995 Symposium, Preventive Strategies for Living in a Chemical World. Plenary sessions and breakout sessions will focus on:

- Risk assessment for human health, including probabilistic analysis. Are the health risks exaggerated?
- Risk assessment for ecological effects.
- Economics of environmental improvement, the costs and benefits.
- Newly emerging chemical health threats.
- Exploration of the myriad ethical aspects of genetic screening for health risk factors.

The Collegium Ramazzini is an international scientific organization of scientists elected to membership because of their contributions to occupational and environmental health.

For additional information, contact:

COLLEGIUM RAMAZZINI
c/o Birch & Davis Associates, Inc. ♦ Attn.: Mollie McEvoy
8905 Fairview Road, Silver Spring, MD 20910-4147 USA
Phone: 01-301-650-0282 or 01-301-589-6760 ♦ Fax: 01-301-650-0398